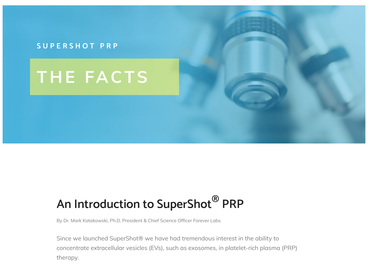

SUPERSHOT PRP

THE FACTS

An Introduction to SuperShot® PRP

By Dr. Mark Kotakowski, Ph.D. President & Chief Science Officer Forever Labs

Since we launched SuperShot® we have had tremendous interest in the ability to concentrate extracellular vesicles (EVs), such as exosomes, in platelet-rich plasma (PRP) therapy.

As a research scientist, I have been studying the therapeutic value of mesenchymal stem cells for 20 years, and exosomes for 10 years, and have developed therapies and filed patents employing both. Several years ago, I became aware of the use of PRP in orthobiologics and began to study and experiment with PRP systems and techniques. Based upon my research experience with exosomes, it struck me that these potent biological molecules were not being leveraged in PRP therapies that included them but didn't concentrate them. As my PhD is in Medical Physics, I turned to physics for a solution. Thus, SuperShot® was born.

In this post, I will address the most asked questions about SuperShot® and give some deeper insight into the rationale and science behind it.

What is SuperShot® PRP?

SuperShot® PRP is a process that concentrates the plasma EVs in PRP. By performing one additional spin of the platelet-poor plasma (PPP), SuperShot® enables the precipitation of low-density lipid-based EVs. Many of the EVs concentrated by SuperShot® are exosomes.

All PRP contains exosomes (and other EVs). Using SuperShot® in the PRP process increases the content of exosomes by concentrating them.

Why doesn't the standard PRP process concentrate exosomes?

Exosomes are not dense enough to be isolated by clinical centrifuges, which typically spin at speeds of 1000-5000 RPM. To precipitate exosomes by centrifugation alone, speeds of >100,000 RPM are required, and it takes several hours. Standard PRP contains exosomes, but they are not concentrated above the patient's basal plasma levels by the normal PRP process.

How does SuperShot® work?

SuperShot employs a physics technique to change the dynamics of plasma centrifugation. The addition of polyethylene glycol (PEG) and a high-weight Dextran (Dex) to plasma creates an aqueous two-phase system that decreases the solubility of low-density lipids (such as exosomes). The exosomes can then readily be pelleted at tabletop centrifuge speeds.

Is SuperShot® solution included in the PRP?

No. The PEG/Dex in SuperShot® solution remains in the depleted PPP, which is discarded. Both the PEG and Dex remain soluble in the PPP. Only the pelleted EVs are added to the PRP.

Is SuperShot® PRP autologous?

Yes. The SuperShot® process concentrates EVs that are in the patient's plasma. Just like concentrating platelets, SuperShot® concentrates what is already in the patient's blood.

Are plasma exosomes a therapeutic component of PRP?

This is an open question. PRP is relatively new itself, and its therapeutic components are still being elucidated. However, there is pre-clinical evidence that suggests that plasma-derived exosomes have therapeutic value. Here are some recent studies of plasma exosomes in animals:

Exosomes Isolated From Platelet-Rich Plasma and Mesenchymal Stem Cells Promote Recovery of Function After Muscle Injury: https://pubmed.ncbi.nlm.nih.gov/32543819/

Plasma exosomes protect the myocardium from ischemia-reperfusion injury: https://pubmed.ncbi.nlm.nih.gov/25881934/

Exosomes derived from platelet-rich plasma promote the re-epithelization of chronic cutaneous wounds via activation of YAP in a diabetic rat model: https://pubmed.ncbi.nlm.nih.gov/28842318/

Plasma-Derived Exosomes Boost the Healing of Irradiated Wound by Regulating Cell Proliferation and Ferroptosis: https://pubmed.ncbi.nlm.nih.gov/33851500/

Exosomes derived from human platelet-rich plasma prevent apoptosis induced by glucocorticoid-associated endoplasmic reticulum stress in rat osteonecrosis of the femoral head via the Akt/Bad/Bcl-2 signal pathway: https://pubmed.ncbi.nlm.nih.gov/28255363/

Could the therapeutic effect of plasma exosomes vary between patients?

Almost certainly. As mentioned above, the individual therapeutic components of PRP itself have not been well-established; however, there is evidence that the effect of PRP varies between patients. *If plasma exosomes underpin the effects of PRP*, then this effect would be expected to vary between patients as well.

As all physicians that employ PRP are aware, different PRP systems and processes result in different PRP preparations. PRP preparations vary in concentrations of leukocytes, RBCs, platelets, proteins, etc., and these vary within the same preparation between patients.

The SuperShot® PRP process enables the concentration of exosomes in the PRP preparation.

Most physicians that use PRP clinically believe that more clinical trials to test applications and various PRP preparations will improve PRP therapy. The new ability to concentrate the EV component in PRP preparation should warrant consideration in clinical investigations as well.

Why are plasma exosomes interesting?

Extracellular vesicles (such as exosomes) are released by cells that efficiently transfer their molecular cargo to other cells. Plasma is rich in exosomes, and it is known that exosomes mediate many physiological functions, including inflammation, angiogenesis, and wound healing. Exosomes contain non-coding RNAs (such as microRNAs) that have potent effect upon acceptor cells that take up the exosomes. Unlike proteins that are used by cells as functional molecules, non-coding RNAs in exosomes can modulate gene expression in acceptor cells. For these reasons, exosomes have generated considerable clinical interest over the past decade, with hundreds of clinical trials testing their therapeutic application.

What is the regulatory status of SuperShot® PRP?

PRP is considered a blood product, per the FDA guidance "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use"; July 2020, Section V.A, pg. 22: *"...for example, platelet rich plasma (PRP; blood taken from an individual and given back to the same individual as platelet rich plasma) is not an HCT/P under 21 CFR Part 1271 because it is a blood product."*

SuperShot® PRP is a PRP preparation, according to the FDA's guidance as: 1) it is a blood product, 2) it is autologous, 3) it is removed from an individual and implanted into the same individual in the same surgical procedure, 4) it does not include intervening processing steps beyond rinsing, cleansing, sizing, or shaping, and 5) it raises no additional risks of contamination and communicable disease transmission beyond that typically associated with surgery.

Please see a Memorandum from Enzyme Corporation and our position paper here.

Does the SuperShot® isolated fraction contain only exosomes?

No. The plasma is rich in exosomes, and exosomes range between 30-150nm in diameter. Many analyses have demonstrated that the SuperShot® isolated fraction is rich in exosomes, and exosomes may be the most abundant EV present. However, there are other EVs isolated by SuperShot® as well, some ranging up to 450nm in size. As an example, some of these EVs are likely platelet-derived microvesicles which are larger than exosomes. Some EVs are created by different processes, however the characterization of EVs is often dependent upon the context in which they are studied.

Exosomes are some of the best studied EVs, and they constitute a large portion, if not the majority of EVs isolated in the SuperShot® fraction. For this reason, we often speak to the exosomes isolated by SuperShot®. That said, the SuperShot® process isolates all low-density EVs from the PPP.

Closing thoughts...

I believe in the therapeutic value of PRP. I know many physicians that use it, and many people that have benefited from it as patients. I believe that the better the components of PRP are understood, and the more fidelity applied to the preparation, the more potential PRP will have clinically.

As a scientist, it excites me that physicians now can concentrate the exosome fraction in their PRP preparation. It is my hope that PRP therapy and most importantly, patient outcomes, can be improved as a result.

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HAVE MORE QUESTIONS ABOUT SUPERSHOT PRP®?

No problem, we have answers.

Don't let billions of exosomes go unutilized. Isolate them with the SuperShot and maximize the regenerative potential of PRP in minutes.

Please fill out the information below and one of the SuperShot PRP team members will be in touch.

LET'S TALK

SUPERSHOT PRP

Got questions? Want to know more about SuperShot PRP?

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